REMARKS

Independent claims 1 and 27 have been amended to limit their applicability to where the ration of the topical corticosteroid cream to the antihistamine is 1:1 or less. Dependent claims 6, 29, 30 and 31 have also been amended.

In the Office Action dated August 18, 2008, the examiner rejected claims 1-6, 12-20, 26-35 and 41-42 under 35 U.S. C. section 103(a) as being unpatentable over Roberts (US5750141) in view of Platt (WO/9810647 A1) in view of McCadden (US 6479 058), O'Kane et al (The Physician and sportsmedicine Sept. 1999 vol. 27(9) pp. 1-14 and Healthchemist (online pharmacy printout or Naphcon being sold).

The essence of the rejection by the examiner is the introduction of the new prior art, namely Platt, and the examiner's contention that it would have been obvious to combine the method steps and composition of Roberts and the combination of pheniramine maleate with either naphazoline HCL or phenylephrine HCL because Platt teaches a topical preparation of an antihistamine and at least one hydrocortisone to treat dermatitis.. It is respectfully contended that the examiner's combination of Roberts and Platt in the context of this invention is incorrect.

Platt, on page 2, teaches that Beadryl®, an antihistamine of diphenhydramine, tends to be deactivated by other active ingredients including by the addition of hydrocortisone. However, on page 5, lines 9-16, Platt goes on to teach that he discovered that if the ratio of the hydrocortisone to the

antihistamine is 4:3 and not more or less the addition of hydrocortisone, rather than decreases, actually greatly increases the absorption rate of the diphenhydramine. On page 6, last paragraph, Platt writes:

> These benefits, however, are greatly reduced as the ratio of the compound moves away from 4:3 .., When the formula contains a greater portion of diphenhydramine, the compound tends to become oversaturated and ineffective, ...

Platt also teaches at page 7 that the antihistamine could also be pheniramine maleate.

In direct contradiction to Platt and the prior art, the present invention, based on experimentation, achieves a dramatic increase in effectiveness and speed by adding pheniramine maleate to hydrocortisone well outside the 4:3 ratio and together with 1 of 2 decongestants - we can increase, not just absorbability but also antihistamine effectiveness. Platt specifically teaches away from doing this and one of ordinary skill would not combine pheniramine maleate and hydrocortisone with the teachings of Roberts because the person of ordinary skill in the art would not add the hydrocortisone and the antihistamine at all, with or without decongestants, because they don't work together outside the ratio as taught by Platt. The hydrocortisone would be expected to deactivate the antihistamine. This is especially true in the present invention which is outside the 4:3 ratio of Platt by orders of magnitude.

For example, "EXAMPLE I" on page 14 of the Specification of the present invention teaches 0.1 gram of 1% hydrocortisone and 1 drop of solution, the solution having 0.32% of antihistamine (pheniramine maleate). Page 12 of the

specification states that one drop is about 0.06 milliliters. Accordingly, if we take 0.32% to mean roughly one third of one per cent, then EXAMPLE I teaches mixing 0.001 gram of hydrocortisone with about 0.002 milliliters of antihistamine

Water at 4°C is defined as exactly one gram per milliliter. We can assume reasonably that Opcon-A® solution is slightly more dense than water and is therefore a bit more than one gram per milliliter. If we make that assumption, then the present invention teaches using 0.001 gram of hydrocortisone with a bit more than 0.002 grams of antihistamine. That is a ratio of a little less than 1:2 of hydrocortisone to antihistamine. This is well outside the limited acceptable range taught by Platt of 4:3 hydrocortisone to antihistamine. The net result is that EXAMPLE I in the present invention uses a roughly 1:2 ratio of hydrocortisone to antihistamine which Platt teaches should *not* be used since it would deactivate the antihistamine and render it less effective. Thus Platt teaches away from the present invention and teaches away from being combined with Roberts to obtain the teachings of the present invention.

EXAMPLE VIII on page 19 of the Specification utilizes a 0.05% corticosteroid with the same Opcon-A® solution. This would result in a ratio of corticosteroid to antihistamine of approximately 1:40, outside the limits of Platt by well over an order of magnitude. The proposed amendment, which recites that the ratio of the topical corticosteroid cream to the antihistamine must be less than 1:1 is nonobvious in relation to Platt and the rest of the prior art in combination with the other elements of the claims. Similarly, dependent claims 6, 29, 30 and 31, which recite that the ratio of the topical corticosteroid cream to the

antihistamine must be approximately 1:40 (see claim 6), less than 1:2 (see claim 29), approximately 1:2 (see claim 30) or between approximately 1:40 and approximately 1:2 (see claim 31) are nonobvious in relation to Platt and the rest of the prior art in combination with the other elements of these claims.

Moreover, unlike the case law cited by the examiner, combining Platt and Roberts are not examples of teaching two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for that very purpose. The case law is speaking of combining prior art references in a manner that is consistent with each of them. In this case, the references would have to be combined in a manner that directs contradicts Platt, in order to end up with the method and composition of the present invention. Accordingly, the cases cited by the examiner are inapposite.

Applicant also respectfully questions the entire viability of Roberts and is suitability as prior art for the following reason. Robert contradicts himself internally in column 6 lines 15-24 versus column 6 lines 25-31. In the first paragraph he says vasodilators *help remove* therapeutic agents and help deeper penetration of the skin by the therapeutic agent. In the next paragraph he says vasoconstrictors *decrease the rate that the therapeutic agent is cleared away/removed* which increases the depth of tissue penetration of the therapeutic agent. Which is it – does less removal of the therapeutic agent increase the depth of penetration of the therapeutic agent or does more removal increase the depth of penetration. They cannot both be true. It is unlikely that the invention of Roberts really works with both vasoconstrictors and vasodilators.

The amendments to the dependent claims 6, 29, 30 and 31 are supported by EXAMPLE I on page 14 of the Specification and EXAMPLE VIII on page 19 of the Specification.

It is respectfully requested that claims 1-6, 12-20, 26-35 and 41-42 are not taught by the combination of the prior art cited and are in condition for allowance. It is hereby requested that the above amendment be entered and that these claims be examined and allowed.

A credit card payment form (PTO-2038) authorizing payment of $245 for a response within the second month, accompanies this Amendment.

Dated: New York, NY
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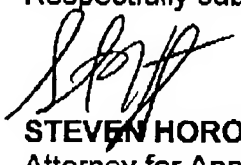
Respectfully submitted,



STEVEN HOROWITZ, ESQ.
Attorney for Applicant
Registration No. 31,768
295 Madison Avenue, Suite 700
New York, NY 10017
(212) 867-6800
(212) 685-6862 fax
sh@patentny.com